

112TH CONGRESS  
1ST SESSION

# H. R. 1897

To amend the Public Health Service Act to require a Federal commitment to Alzheimer’s disease research to advance breakthrough treatments for people living with Alzheimer’s disease.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 13, 2011

Mr. SMITH of New Jersey (for himself, Mr. MARKEY, Mr. BURGESS, and Mr. PLATTS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Public Health Service Act to require a Federal commitment to Alzheimer’s disease research to advance breakthrough treatments for people living with Alzheimer’s disease.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Alzheimer’s Break-  
5 through Act of 2011”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

1           (1) Alzheimer’s disease is a disorder that de-  
2           stroys cells in the brain. The disease is the leading  
3           cause of dementia, a condition that involves gradual  
4           memory loss, decline in the ability to perform rou-  
5           tine tasks, disorientation, difficulty in learning, loss  
6           of language skills, impairment of judgment, and per-  
7           sonality changes. As the disease progresses, people  
8           with Alzheimer’s disease become unable to care for  
9           themselves. The loss of brain cells eventually leads  
10          to the failure of other systems in the body.

11          (2) Alzheimer’s disease is the sixth leading  
12          cause of death in the United States and remains the  
13          only one of the top ten causes of death without an  
14          identified way to prevent, cure, or slow its progres-  
15          sion.

16          (3) An estimated 5.4 million Americans have  
17          Alzheimer’s disease. With the aging of the baby  
18          boomers, the number of Americans with Alzheimer’s  
19          disease will likely reach 13.5 million in 2050—and  
20          could be as high as 16 million.

21          (4) An individual will live with the increasingly  
22          devastating, debilitating, and destructive effects of  
23          Alzheimer’s disease for an average of 4 to 8 years  
24          after diagnosis, and some live as long as 20 years.

1           (5) Alzheimer’s disease does not just affect  
2 those with the disease but takes an emotional, finan-  
3 cial, and physical toll on caregivers. In 2010, nearly  
4 15 million Americans provided 17 billion hours of  
5 unpaid care to family members and friends with Alz-  
6 heimer’s disease and other dementias at a total  
7 value of over \$202 billion.

8           (6) In 2011, Medicare is expected to spend \$93  
9 billion for the care of individuals with Alzheimer’s  
10 disease and other dementias and this amount is pro-  
11 jected to increase to \$627 billion in 2050. Medicaid  
12 costs is expected to increase nearly 400 percent,  
13 from \$37 billion in 2011 to \$178 billion in 2050.

14           (7) In fiscal year 2010, the Federal Govern-  
15 ment spent \$450 million on Alzheimer’s disease re-  
16 search. For every \$100 the Federal Government  
17 spent on Alzheimer’s disease research in fiscal year  
18 2010, Medicare and Medicaid spent more than  
19 \$28,000 for care for people with Alzheimer’s disease.

20           (8) Research leading to treatments that delay  
21 onset of Alzheimer’s disease by just five years would  
22 cut Federal Government spending on the disease by  
23 45 percent in 2050.

24           (9) In 2010, Congress passed the National Alz-  
25 heimer’s Project Act, which instructs the Depart-

1       ment of Health and Human Services to develop a  
2       strategic plan (referred to in this section as the  
3       “National Alzheimer’s Project plan”) to address the  
4       rapidly escalating Alzheimer’s disease crisis.

5               (10) The annually updated National Alz-  
6       heimer’s Project plan must be transmitted to Con-  
7       gress each year and is to include outcome-driven ob-  
8       jectives, recommendations for priority actions, and  
9       coordination of all federally funded programs in Alz-  
10      heimer’s disease research, care, and services.

11              (11) It is expected that the National Alz-  
12      heimer’s Project plan will include research priority  
13      actions to accelerate the development of treatments  
14      that would prevent, cure, or slow the progression of  
15      Alzheimer’s disease.

16              (12) The medical and research communities  
17      have the ideas, the technology, and the will, but need  
18      the Federal Government to commit to an innovative  
19      research approach, to find breakthroughs that will  
20      provide significant returns on investment and will  
21      save millions of lives.

1 **SEC. 3. REQUIRING A FEDERAL COMMITMENT TO ALZ-**  
2 **HEIMER'S DISEASE RESEARCH.**

3 (a) IN GENERAL.—Part A of title IV of the Public  
4 Health Service Act (42 U.S.C. 281 et seq.) is amended  
5 by adding at the end the following new section:

6 **“SEC. 404I. REQUIRING A FEDERAL COMMITMENT TO ALZ-**  
7 **HEIMER'S DISEASE RESEARCH.**

8 “(a) DEFINITION OF ALZHEIMER'S.—In this section,  
9 the term ‘Alzheimer’s’ means Alzheimer’s disease and re-  
10 lated dementias.

11 “(b) PURPOSE.—The purpose of this section is to de-  
12 velop and execute a scientific research plan to accelerate  
13 breakthroughs in treatments that prevent, cure, or slow  
14 the progression of Alzheimer’s disease and reduce the fi-  
15 nancial burden of Alzheimer’s on federally funded pro-  
16 grams and families.

17 “(c) FEDERAL COMMITMENT TO ALZHEIMER'S DIS-  
18 EASE RESEARCH.—For the purpose described in sub-  
19 section (b), the Director of NIH shall coordinate and focus  
20 all Alzheimer’s research activities of the National Insti-  
21 tutes of Health. Such activities shall include the following:

22 “(1) The establishment of a strategic Alz-  
23 heimer’s research plan—

24 “(A) to expedite therapeutic outcomes for  
25 individuals with or at risk for Alzheimer’s,  
26 using scientifically based strategic planning, for

1 the conduct, coordination, and support of the  
2 Alzheimer’s research portfolio within the Office  
3 of the Director of NIH and across all Institutes  
4 and Centers of the National Institutes of  
5 Health; and

6 “(B) that, with respect to such Alzheimer’s  
7 research—

8 “(i) identifies research opportunities  
9 relating to emerging science, knowledge  
10 gaps, and priorities of the National Insti-  
11 tutes of Health and provides recommenda-  
12 tions for conducting such research;

13 “(ii) identifies opportunities to incor-  
14 porate Alzheimer’s disease research in all  
15 relevant aging, neuroscience, basic, clinical,  
16 and translational science initiatives carried  
17 out by the National Institutes of Health,  
18 including initiatives that are trans-Na-  
19 tional Institutes of Health, innovative, and  
20 nontraditional initiatives;

21 “(iii) improves existing Alzheimer’s  
22 programs and initiatives at the National  
23 Institutes of Health, including consolida-  
24 tion or expansion of program activities, if  
25 such consolidation or expansion would im-

1 prove program efficiencies and research  
2 outcomes;

3 “(iv) identifies gaps in the supporting  
4 infrastructure and the coordination of the  
5 Alzheimer’s research portfolio across the  
6 Institutes and Centers of the National In-  
7 stitutes of Health, including the Alz-  
8 heimer’s Disease Centers and Alzheimer’s  
9 Disease Research Centers and all intra-  
10 mural and extramural Alzheimer’s-related  
11 activities;

12 “(v) identifies public-private partner-  
13 ship opportunities to expedite the develop-  
14 ment of mechanisms for early diagnosis  
15 and therapies and assistive technologies for  
16 Alzheimer’s, including such therapies and  
17 technologies that demonstrate high promise  
18 of substantially slowing, stopping, or re-  
19 versing Alzheimer’s and reducing the  
20 amounts that the Federal Government  
21 would spend on the future care provided to  
22 individuals who develop Alzheimer’s;

23 “(vi) identifies opportunities to in-  
24 crease research and improve clinical out-

1 comes for women and minority populations  
2 at high-risk of developing Alzheimer’s; and

3 “(vii) incorporates the research pri-  
4 ority actions identified by the Secretary  
5 and Advisory Council on Alzheimer’s Re-  
6 search, Care, and Services in the report  
7 submitted by the Secretary to Congress  
8 under section 2(g) of the National Alz-  
9 heimer’s Project Act (42 U.S.C.  
10 11225(g)).

11 “(2) The provision of budget estimates, without  
12 regard to the probability that such amounts so esti-  
13 mated will be appropriated, including—

14 “(A) budget estimates of the amounts re-  
15 quired for the Institutes and Centers of the Na-  
16 tional Institutes of Health to carry out all Alz-  
17 heimer’s activities identified in the strategic re-  
18 search plan developed under paragraph (1);

19 “(B) budget estimates of the amounts re-  
20 quired to carry out all identified research pri-  
21 ority actions described in paragraph (1)(B)(vii);  
22 and

23 “(C) identification of funds in the existing  
24 budget of the National Institutes of Health to  
25 accomplish Alzheimer’s activities identified by



1           the strategic research plan developed under  
2           paragraph (1).

3           “(d) PUBLIC-PRIVATE PARTNERSHIPS.—In providing  
4 for Alzheimer’s research activities, the Director of NIH  
5 and the Directors of Institutes and Centers of the Na-  
6 tional Institutes of Health conducting Alzheimer’s re-  
7 search, shall make available contracts, grants, or coopera-  
8 tive agreements to facilitate partnerships between public  
9 and private entities, which may include private or public  
10 research institutions, institutions of higher education,  
11 medical centers, biotechnology companies, pharmaceutical  
12 companies, disease advocacy organizations, patient advo-  
13 cacy organizations, or academic research institutions.  
14 Such partnerships may be established for, but not limited  
15 to, any of the following purposes:

16           “(1) To execute the Alzheimer’s research plan  
17           established under subsection (c)(1).

18           “(2) To support the development of diagnostic  
19           technologies and protocols to encourage early diag-  
20           nosis of individuals at risk for Alzheimer’s and to  
21           permit the tracking of the progression of Alzheimer’s  
22           in asymptomatic or symptomatic populations.

23           “(3) To develop and diffuse data sharing prac-  
24           tices that accelerate the advancement of knowledge

1 and understanding of the pathogenesis, progression,  
2 prevention, and treatment of Alzheimer's.

3 “(e) REPORTING.—

4 “(1) The Director of NIH shall annually report  
5 to the Secretary, the Advisory Council on Alz-  
6 heimer's Research, Care, and Services, and the ap-  
7 propriate committees of jurisdiction in Congress, on  
8 the strategic research plan and budget estimates  
9 under subsection (c).

10 “(2) The Director of NIH shall, as part of its  
11 annual request for appropriations to the Office of  
12 Management and Budget, submit to the Office of  
13 Management and Budget and the Committees on  
14 Appropriations of the House of Representatives and  
15 the Senate a report which—

16 “(A) includes budget estimates developed  
17 under subsection (c)(2);

18 “(B) subject to subparagraph (C), includes  
19 requests for amounts to be appropriated for all  
20 Alzheimer's activities identified in the strategic  
21 research plan under subsection (c)(1);

22 “(C) includes, in the case a request is not  
23 made under subparagraph (C) for an activity  
24 identified in such strategic research plan, a full

1 justification explaining why such request was  
2 not made; and

3 “(D) analyzes the progress made toward  
4 accelerating breakthroughs in treatments that  
5 would prevent, cure, or slow the progression of  
6 Alzheimer’s and reducing spending on Alz-  
7 heimer’s care under federally funded programs  
8 and families and identifies any remaining hur-  
9 dles to accelerating such breakthroughs or re-  
10 ducing such financial burden.”.

11 (b) ALZHEIMER’S DISEASE CENTERS.—Section  
12 445(a)(1) of the Public Health Service Act (42 U.S.C.  
13 285e–2(a)(1)) is amended—

14 (1) by inserting “, translational” after “basic”;  
15 and

16 (2) by inserting “and of outcome measures, and  
17 disease management” after “treatment methods”.

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